Patient-generated Data Hearing
HIT Policy Committee, Meaningful Use Workgroup
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Thank you for inviting me to testify today. I serve as director of Project HealthDesign, a national program of Robert Wood Johnson Foundation's Pioneer Portfolio. I last testified before this committee in April 2010 as the Meaningful Use Workgroup endeavored to finalize criteria for Stage 1 of CMS' incentive program for the meaningful use of electronic health records (EHRs). At that time, we worked together to envision future steps needed to ensure that the Meaningful Use program will improve health care and benefit patients as well as clinicians. Since that time, the Workgroup has made considerable strides toward those goals.

Today, we at Project HealthDesign support the Workgroup as it envisions how to incorporate the use of patient-generated data in the clinical setting into Stage 3 of the Meaningful Use program. Criteria related to patient-generated data will help clinicians and institutions see the full benefit of the meaningful use of health IT. Additionally, although the Meaningful Use program has begun to take small steps to support patients and clinicians as they work together across domains, criteria supporting the clinical integration of patient-generated data will further benefit this partnership, as well as the business and technology of health and health care.

My testimony today draws upon the experiences of all fourteen Project HealthDesign teams throughout our two rounds of funding, as well as the teams' interactions with hundreds of patients. However, I will focus mainly on the work of our five current teams. I wish to make the following points:

1. We need to expand the idea of patient-generated data to include patient-defined data.
2. Sharing patient-defined data with clinicians improves the business of health care.
3. Existing technologies are adequate but not optimal for the clinical integration of patient-defined and patient-generated data.

About Project HealthDesign

When Project HealthDesign began in 2006, and as we engaged our first nine grantee teams, we set out to investigate the power and potential of personal health records (PHRs). We had envisioned PHRs as platforms built on data that would enable third-party apps tailored to patient needs. Instead, through a user-centered design process, we discovered that the data we needed to drive the apps came less from the medical record and more from patients' observations about diet, activity, sleep, mood, pain, and medication usage; we called these observations of daily living (ODLs).

For more than six years, and with $10 million in funding, Project HealthDesign has worked with hundreds of patients across a wide variety of age groups to spur innovation in the use of personal health technologies. Our five current teams are BreathEasy at RTI International; Chronology.MD at University of California, Berkeley; dwellSense at Carnegie Mellon University; Estrellita at University of California, Irvine; and iN Touch at San Francisco State University (for more information, refer to Fig. 1 or the Appendix). Each team has worked with populations from different age groups and with different chronic conditions, and has garnered important insights regarding the business and technical aspects of patient-generated data. Following a design-demonstrate-evaluate process, they have provided the tools for more than 135 patients with chronic diseases to capture, display and use their ODLs, and are examining the impact of the inclusion of ODLs on participants' health and health care. As shown in the table below, the studies included a variety of patients, ranging from infants to teens to elders. Participants were socioeconomically diverse, and most were only moderately technologically fluent.

Fig. 1: Current Project HealthDesign teams

Team	BreathEasy	Chronology.MD	dwellSense	Estrellita	iN Touch
Population	Low-income adults ages 20-50 with asthma	Adults ages 20-50 with Crohn's disease	Low-income elders ages 55+ at risk for cognitive decline	High-risk infants and their primary caregivers	Low-income teens and young adults managing obesity
Select ODLs	Peak flow, rescue meds, triggers	Abdominal pain, energy level, activity	Medication taking, phone use, coffee making	Bonding, fussiness, diaper changes	Activity, socialization, mood
Devices given to patients for ODL tracking	Smartphone	iPad	Household sensors, tablet computer	Smartphone	iPod Touch
Data storage platform	RTI server	Amazon EC2 cloud hosting	CMU server	Microsoft HealthVault	TheCarrot.com
Integration into care	Nurses reviewed ODL data weekly via clinician dashboard	Patients prioritized ODL data, clinicians and patients reviewed and discussed select ODL data visualizations during visits	Patients shared ODL data summaries during visits	Nurse case manager reviewed ODL data daily via dashboard	Lay health coach regularly reviewed ODL data summaries

The Value of Patient-generated Data

Through Project HealthDesign, we have discovered that patient-generated data like ODLs matter because they allow clinicians to see a richer picture of the patient's day-to-day health, which leads to better clinical decision-making. ODLs provide a form of data that patients define for themselves, generate, and then submit. In several projects, the types of ODLs that were important to clinicians varied from the lists recommended by patients. For example, Chronology.MD participants valued ODLs about pain and energy levels, but clinicians participating in the study said that the pain and energy level ODL data would not assist them in their treatment decisions.

Although we have explicitly focused on ODLs in Project HealthDesign, we also recognize that other types of patient-generated data contribute to a full picture of a patient's day-to-day health experience. Data resulting from clinician-directed patient self-monitoring of signs and symptoms (e.g., blood pressure, blood glucose), and patient-generated sensor data are two other important examples. Our work has shown that patient-generated data matter to the individuals who capture them, and they matter because they strengthen the patient-clinician partnership by allowing clinicians to see a more robust picture of the individual's day-to-day health experience. To illustrate the value of patient-generated data, please consider the following examples from Project HealthDesign's BreathEasy and iN Touch studies.

Improving Clinical Decision-making

In Project HealthDesign's BreathEasy study, patients with asthma used a smartphone application to track ODLs about use of maintenance and rescue medications, asthma symptoms and triggers, and physical activity. Because a trusted pathway for ODL data was in place to carry the data from the patient participants to nurses, the nurses flagged two reports that caused a physician to reassess two participants' diagnoses and change them from asthma to chronic obstructive pulmonary disease (COPD). Also, when reviewing one patient's data in the clinician dashboard, a clinician noticed that the patient had confused her maintenance and rescue medications; this clinician was able to educate the patient about correct usage.

Improving Patient Self-management

In Project HealthDesign's iN Touch study, obese teens and young adults tracked ODLs (such as information about their physical activity levels, socializing, and moods) in a mobile application on iPod Touch devices. A lay health coach regularly reviewed the data and met with participants to discuss their goals. Participant "Sarah," a high school senior, recorded 117 ODLs during the 6-month study period. She also used the notes section of the app to intensively journal about her path to a healthier life. She regularly text messaged the health coach and met with her to discuss her progress, challenges, and goals. The mobile app, along with the in-person and text messaging support from the health coach, helped Sarah change her habits and lose more than 20 pounds during the 6-month study period.

These two teams' experiences, among others, illustrate the value of ODLs. The ODLs mattered to patients because they allowed them to define their health statuses and progress in their own

ways. They also mattered to clinicians, because the ODL data provided them with clinically relevant signals and a richer picture of the patients' day-to-day health.

Patient-generated Data and Clinical Care

Each of our current grantee teams has taken a unique approach to incorporating patient-generated data into the clinical workflow. However, we have realized that getting patient-generated data into the clinical workflow does not always mean that *all* patient-generated data must enter the EHR. It is most important to incorporate the appropriate amount of data and provide documentation to support the clinical chain of reasoning. Even when patient-generated data does not enter the EHR, it may still enter the clinical workflow during clinical visits or through other technologies that allow access to the data or data summaries. The following examples illustrate that even though the BreathEasy and Chronology.MD teams did not integrate patient-generated ODL data directly into the clinical record, their approaches still allowed clinicians to see and benefit from the data.

The BreathEasy team provided asthma patients a smartphone and mobile application to self-track their ODLs. The resulting ODL data resided on a server at RTI, and clinicians participating in the study accessed a clinician dashboard to view summaries of the data. Nurses at the study's clinical sites followed a protocol to review and triage these summary reports on a weekly basis. If data were out of range, they then scheduled an appointment with the patient or flagged the report for additional review by a physician. When clinicians viewed the clinician dashboard, they had the option to make a note in the patient's EHR when the data lead them to follow up with the patient in any way. However, in most cases, the ODL data and the summary reports in the clinician dashboard did not enter the EHR. In the Chronology.MD study, adult Crohn's patients received an iPad loaded with two mobile apps. Participants used the Chronology app to track their ODLs on a daily basis. The Crohnograph app allowed participants to create customized data visualizations to share with clinicians during visits. The ODL data did not enter the EHR until a clinician entered notes during a clinical visit.

Integrating Patient-generated Data into the EHR

When patient-generated data does need to enter the EHR to support clinicians' chains of reasoning for clinical decision-making, this may happen through direct entry by a clinician, or by integrating portions of the data or data summaries into the EHR. Clinicians will want sufficient documentation of patient-generated data to be able to show the chain of reasoning upon which their diagnoses and treatment decisions rested. More research is needed to determine when patient-generated data must enter the EHR and when it does not need to enter the EHR. Additional research is also needed to identify best practices for sorting, summarizing and safely storing the data.

In Project HealthDesign's iN Touch study, teens and young adults recorded ODLs in a modified version of TheCarrot mobile app, on iPod Touch devices. In this project, and for participants who were patients at San Francisco General Hospital teen or pediatric clinics, monthly summary reports based on the patient's ODL data entered the EHR at SFGH. These pdf reports included

the patient participant's clinical ID number, which allowed research team members to manually reconcile the numbered pdf from the clinical document management server with the correct clinical record. The ODL data remained outside of the EHR, in TheCarrot.com.

Many of our current grantee teams faced two common challenges to integrating the ODL data into the clinical EHR: timing and clinician behaviors. At least three of the five current teams learned from their clinical sites' IT teams that the clinical institutions were in the midst of new EHR implementations or significant changes to existing EHR systems. These timing issues precluded many of the teams from integrating the data or data summaries into the clinical EHR.

The iN Touch team was able to integrate pdf summaries of the participants' ODL data into the EHR, but because the hospital was in the midst of significant work on it EHR system, the team ended up working around several issues (e.g., matching the patient ID on the pdf report in the clinical document server to the correct patient record in the EHR system) because the clinical IT staff was occupied with other issues.

Additionally, some clinicians and/or clinical partner sites were hesitant to incorporate the raw ODL data into the EHR because they thought the chain of trust for the data would be unclear, or because they thought it would be difficult to document the provenance of the patient-generated data.

Patient-generated Data and the Current Technology Landscape

Each of our current teams implemented a unique approach to technologies and systems in its study. Across the teams, however, we intentionally encouraged the adoption of existing devices and publicly available data storage solutions. Even as the available technologies change and evolve over time, our teams have demonstrated that technology is not a barrier; many different combinations of technologies can comprise workable solutions. However, we continue to call for a safe and stable storage place for patient-generated data. Once a safe storage solution is in place, many apps could run off of the same data.

Despite the variety of visualizations our teams employed for data reports or summaries, we have learned that we still need a lot of research and work in the area of data analytics and visual representation. Because there are no existing standards in this area, clinicians could become distracted or burdened when reviewing patient-generated data. These data must be not only understandable, but also usable and useful for clinicians. Visualizations will also need to allow clinicians to review the data quickly.

Patient-generated Data from a Business Perspective

As health care business models begin to shift from fee for service to pay for performance (e.g., Accountable Care Organizations, Patient-centered Medical Homes), technologies that facilitate the use of patient-generated data could emerge as important approaches to patient self-management and as important tools for patient case management outside of clinical visits. Someday, clinicians could prescribe mobile apps to patients and partner with patients to set

targets for ODL data or other patient-generated data. Our current teams' mobile apps serve only to capture and display data. In the future, however, mobile apps might include automated recommendations based on algorithms. Our current teams have demonstrated that ODL data is available from patients and is a trustable source of information for both patients and clinicians.

As the Meaningful Use program has progressed, the business model for EHR system vendors has evolved into a packaged IT system that can be sold. It is unlikely that we will see a business case for an EHR vendor to redesign its system to incorporate patient-generated data at a granular level. Therefore, we call for Meaningful Use criteria supporting the incorporation of patient-generated data into the EHR. However, we must remember that there is currently no compelling reason to store all patient-generated data within the EHR. Instead, we recommend functionality that would document the clinician chain of reasoning when it rests upon patient-generated data. In this way, all of the raw patient-generated data would not need to enter the EHR; only data summaries relevant to a clinician's decision-making process would be documented within the EHR.

Many individuals already engage in self-tracking, and this type of patient engagement represents a new market for health care technologies. In fact, many businesses are already making the most of this opportunity. A better understanding of patients' daily experiences could provide valuable information about medication taking behaviors and provide a mechanism for post-market surveillance of medical devices. The full range of the kinds of businesses that could grow out of patient-generated data is still unknown.

Throughout Project HealthDesign's history, we have intentionally chosen to focus on the value of patient-generated data such as ODLs and the impact of these data upon clinical care. Accordingly, we have also intentionally chosen not to focus on business models for each of our grantee teams' approaches. Even so, we believe our current teams' experiences may provide insight into the cost consequences for working with patient-generated data. Please refer to the following figures for cost- and device-related insights.

Fig. 2: Estimated costs to implement an ODL data system with clinicians

Team	dwellSense	Estrellita	iN Touch
Cost for clinician training time	1 hour per clinician		
Costs for clinician use time	2 minutes per clinician per patient visit (e.g., nurse, pharmacist, PCP)	0.04 FTE at $40+/hour plus benefits for nurse case manager to incorporate system into clinical practice	0.5 FTE at $42,000 plus benefits for a lay health coach, per 100 patients
Cost to integrate ODL reports into EHR	Unknown		
Costs for clinical workflow changes	Once reports are integrated into the EHR, costs are minimal.	Daily data review by a nurse, follow-up actions as needed	

Fig. 3: Estimated costs to build ODL data system and implement it with patients

Team	BreathEasy	Chronology.MD	dwellSense	Estrellita	iN Touch
Cost to build devices			Sensor engineering: 6 person-months		
Cost to build and maintain applications	Programming and maintenance: $145,000	Development: $200,000 Technical oversight from clinical staff, research/evaluation team: $200,000-400,000 for 18 to 24 months	Programming and testing: 180 person-hours	Programming and testing: 1,280 person-hours Ongoing app/system maintenance: 0.1 FTE (programmer)	Modifications to existing TheCarrot mobile application: $50,000
Cost for data storage/ processing			$5/patient per month, or $0 if stored in MS HealthVault	Cloud hosting, unknown, per user	
Cost to implement system with patients		Devices and hardware (iPad or other tablet, Fitbit Body monitor, Withings scale): $700/patient	Hardware: ($200 sensors/appliances + $200 for cheap tablet computer + $250 for cheap PC + Internet) = cost per household		
Cost for technical support				Unknown, per user	

Fig. 4: Device-related insights

Team	BreathEasy	Chronology.MD	Estrellita	iN Touch
Devices	Smartphone (Samsung Captivate)	iPad, Fitbit Body Monitor, Withings Scale	Smartphone (T-Mobile G2)	iPod Touch
Insights	Data plans are expensive. Android platform is easy to program. Battery life was still a concern; we modified the study design to include fewer devices. Population adapted to smartphone use quickly and with relatively few technical issues.	Patients liked using their iPads, and the screen size afforded patients a clear and appropriately sized visual image of the data. Patients liked using the Fitbit Body Monitor and the Withings scale. The Withings API changed twice during the 6-month study; adapting the system to the new APIs required additional developer time.	Caregivers did not have any trouble learning to use the smartphone and app, and they reported that it was easy and convenient for them to carry the smartphone with them and input data whenever they had time. Battery life was not an issue. It was not feasible to train multiple caregivers to use the same smartphone to track ODLs.	Because the iPod Touch operates on Wi-Fi, a data plan is not necessary. Data plan costs and device costs for smartphones would have been a barrier for the low income youth population enrolled in the study. Wi-Fi was adequate, although it was a barrier for a few participants to find Wi-Fi as needed.

I appreciate the opportunity to provide this testimony to the Meaningful Use Workgroup as it works to envision Stage 3 of the Meaningful Use program. Please do not hesitate to let me know when opportunities arise for us to assist the workgroup in the future. We at Project HealthDesign are eager to facilitate your progress as the Workgroup carries forward this important vision for patient-generated data and its integration into the EHR.

For more information about our program, please visit projecthealthdesign.org.

Appendix: Current Project HealthDesign Grantee Teams

BreathEasy
RTI International and Virginia Commonwealth University
Principal Investigators: Barbara Massoudi, M.P.H., Ph.D.; Stephen Rothemich, M.D.

Asthma is a common chronic illness that affects more than 23 million adults in the U.S. In addition to respiratory symptoms associated with the disease, individuals with asthma are also more likely to experience depression and anxiety. The BreathEasy team has designed a mobile application that builds on the latest clinical guidelines for treatment and self-monitoring for patients with asthma. Patients use the application on smartphones to capture and report observations of daily living (ODLs) such as use of controller and rescue medications, symptom

levels, quality of life and smoking. Clinicians utilize a Web-based dashboard with simple analysis and visualization tools that allow them to quickly view the patients' data, evaluate their health statuses and communicate changes in treatment or monitoring. By providing a clearer picture of their health in everyday life, both patients and clinicians use the ODL data to make lifestyle and treatment adjustments and better manage asthma symptoms.

BreathEasy's Technical Architecture
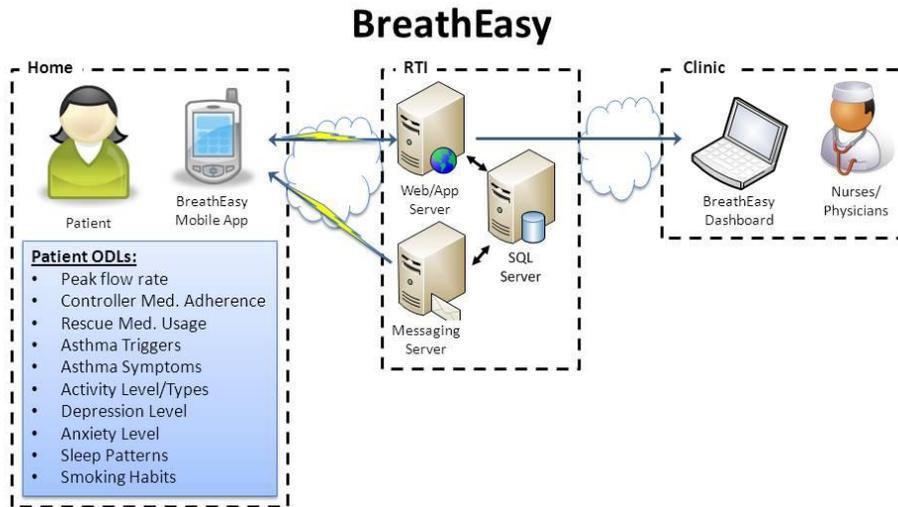
Chronology.MD
University of California, Berkeley, Healthy Communities Foundation, University of California, San Francisco
Principal Investigators: Deryk Van Brunt, M.P.H., Dr.P.H.; Linda Neuhauser, M.P.H., Dr.P.H.; Jonathan Terdiman, M.D.

More than 600,000 people in the U.S. live with Crohn's disease, a chronic and progressive disorder of the digestive system. The disease is most prevalent in young adults ages 18–35 and can be complicated and expensive to treat. Significant social and emotional implications may also result from the disease. The Chronology.MD team has created two mobile applications to help young adults who have Crohn's disease create visually aided narratives of their conditions and responses to treatment. Using iPads and other mobile devices, the project enables patients to self-track ODLs such as pain and energy levels alongside clinical symptoms or measurements, such as B12 levels. Chronology.MD allows patients to effectively communicate patient narratives that can help increase the quality of the patient's life and health.

In this study, patients tracked ODL data in the Chronology app, using iPads. The resulting data then resided on an Amazon cloud server. Later, using the Crohnograph app, participants looked for trends among the ODL data and created custom visualizations. When participants went in

for clinical visits, they brought the visualizations to discuss with their providers. During the visit, clinicians documented information about the visualizations or the related conversations as a note in the EHR.

Chronology.MD's Technical Architecture
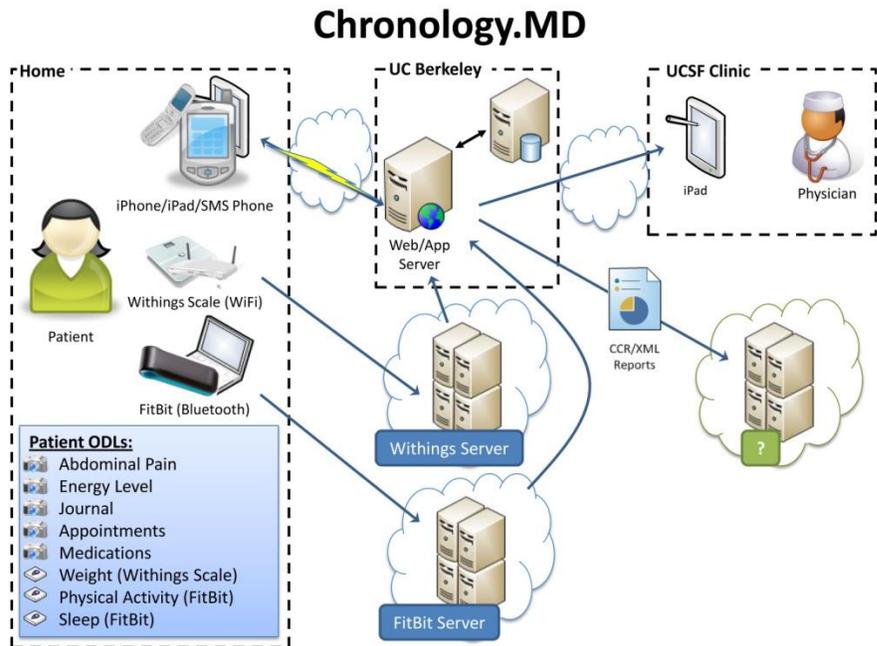
**dwellSense**
Carnegie Mellon University
Principal Investigator: Anind Dey, Ph.D.

It is often hard to detect subtle changes in everyday activities — such as the loss of the ability to make a sandwich, dial a phone, or take medications correctly — that could indicate the onset of dementia or physical decline in adults who live alone. The dwellSense team has developed new technologies that monitor the routines of elders who are at risk for cognitive decline. In-home sensors monitor routine tasks, such as taking medications, making phone calls and preparing coffee, and provide trustworthy data for long-term cognitive and functional assessment. This sensor data is then used by key stakeholders, including participants, caregivers and clinicians, to detect and better understand the individual's changing cognitive and physical abilities. By identifying decline at an early stage, caregivers have a chance to halt or even reverse deterioration that might otherwise result in an unsafe living situation or a transition to long-term care.

In this study, wireless sensors captured ODL data about routine daily activities and sent data to a nearby laptop computer, which enabled the process to occur automatically and unobtrusively. The sensor data were then encrypted and transmitted from the in-home laptop to a server at Carnegie Mellon University. From the server, custom applications turned the data

into visualizations for both the patients (via in-home tablet displays that showed visual representations of nearly real time views of that day's data) and their clinicians. The positive findings were that the individuals who saw daily performance scores based on their ODL data had a better overall awareness of their abilities and better overall functional performance scores. Those who saw their historical performance once every 4 months (during the last 4 months of the study) gained some short-term benefit, but the benefit did not endure.

dwellSense's Technical Architecture
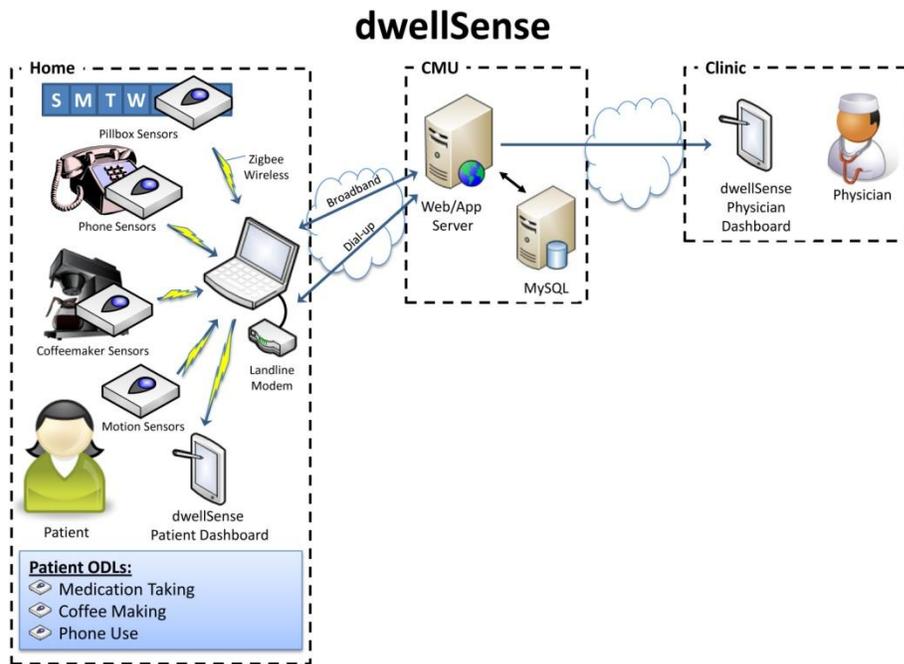
**Estrellita**
University of California, Irvine
Principal Investigators: Gillian Hayes, Ph.D.; Karen Cheng-Ramos, Ph.D.

Early health decisions for high-risk infants can make a big difference in how well they do down the road. The Estrellita team has created a mobile application to collect information from high-risk infants and their caregivers. This app allows the caregivers to more easily interface with clinicians to improve care and communication. Caregivers use the Estrellita app to record ODLs like the baby's temperament, diapering, and weight as well as caregiver ODLs like stress levels and risk for post-partum depression. Estrellita also helps caregivers manage communication with clinicians by tracking clinical appointments and encouraging them to review the ODL data and ask questions during appointments.

In this study, at least one nurse case manager at the study's clinical site logged in to the Estrellita clinician dashboard on a daily basis to review the babies' ODL data. This clinician dashboard resided outside of the clinical EHR system and enabled both overview and detailed views of the ODL data. If the nurse case managers identified causes for concern (e.g., an

insufficient number of diapers, infant weight loss), they followed up with the caregivers directly to provide feedback and help address the problem. Additionally, alerts were sent as emails to the EDAC nurse case managers and specified pediatricians when certain thresholds were met. This team used a standard smartphone and designed the Estrellita dashboard (viewable by nurse case managers and specified pediatricians) for display on desktop and laptop computers. Caregivers were able to access all of the ODL data through their individual Microsoft HealthVault accounts; they could also view simple visualizations through the mobile application.

Estrellita's Technical Architecture
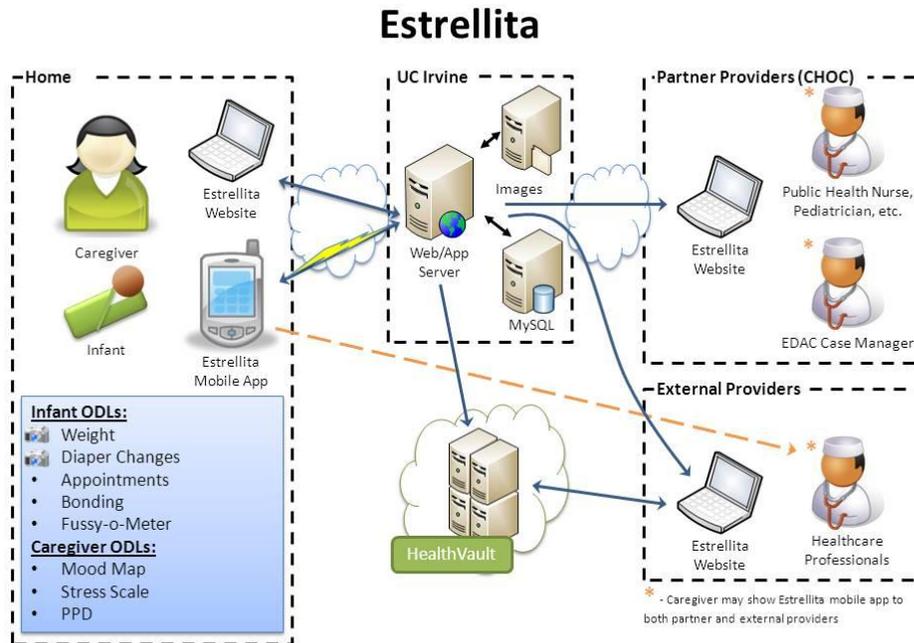
iN Touch
San Francisco State University
Principal Investigators: Katherine Kim, M.P.H., MBA; Christina Sabee, Ph.D.

Teens and young adults from low-income backgrounds are disproportionately affected by obesity. iN Touch examines how collecting ODLs using a mobile app for the iPod Touch impacts low-income teens and young adults who are managing obesity. The project utilizes apps and other emerging technologies that are popular among young people to make monitoring ODLs – such as physical activity, food intake, socialization and mood – more convenient. In addition, the technology allows participants to easily share the data with their health coaches and clinical care teams in order to help set health goals, track their progress and ultimately improve their health.

In this study, teen and young adult participants recorded ODL data through a slightly customized version of TheCarrot mobile application. The ODL data itself resided on TheCarrot

platform. Participants reviewed their ODL data through TheCarrot.com interface or via the mobile application. A lay health coach met regularly with participants to discuss their goals and review their ODL data, and the health coach had access to participants' data summaries and ODL data via TheCarrot.com interface. Clinical partners at San Francisco General Hospital had access to summary reports of participants' ODL data via TheCarrot.com interface and later through the participants' clinical records in the hospital's EHR.

iN Touch's Technical Architecture